

reduce the incidence or severity of a chronic immune mediated disorder, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, said kit further comprising labeling indicating that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal to which one or more doses of said immunogens are administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder, wherein said schedule, according to said instructions, calls for the first dose of an immunogen to be given before 42 days after birth.

E 39. The ~~kit~~ of claim ~~38~~, at least one of said immunogens also acting to substantially reduce the incidence or severity of an infectious disease to which said mammal is susceptible.

E 40. The ~~kit~~ of claim ~~38~~ wherein said instructions state that the kit is to be used to reduce the incidence or severity of diabetes or systemic lupus erythematosis.

41. A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at specific times after birth, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal, the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

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where said immunogens are administered from a kit according to  
~~claim 38.~~

#### **REMARKS**

New claims 38-40 are "kit" claims reciting that the kit includes both immunogens and labeling (a) stating that the immunogens are useful, when used as directed, to reduce the incidence or severity of a chronic immune-mediated disorder (38), particularly diabetes or SLE (38), and (b) giving instructions for the use of the immunogens to achieve the stated purpose.<sup>1</sup>

#### 1. Indefiniteness

The claims have been amended to overcome the indefiniteness rejections as indicated below.

Claim 2 has been amended to replace "immune mediated disorder" with "diabetes", consistent with the preamble of claim 3 as amended April 10, 1995.

Claim 7 has been amended to recite use of at least one immunogen other than a BCG or smallpox immunogen.

Claim 9 has been amended to depend on claim 3.

Claims 11-14 have been amended to replace "the disorder"

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<sup>1</sup> Such limitations are proper under *In re Gulack*, 217 USPQ 401, 403 (Fed. Cir. 1983), and "label" limitations appear in many issued patents, including Olney, USP 5,011,853 (claim 18--"a label which indicates that said pharmaceutical agent can be used for reducing the neurotoxicity of at least one cholinergic neurotoxin"); Kelly, USP 5,208,031 (claim 4-- "the packaging material indicates that the sexual lubricant mixture... can reduce the risk of being infected by at least one type of sexually transmitted virus"); Sanders, USP 4,820,635 (claim 1-- "A kit... comprising... instructions for performing the assay"). New claim 41 is directed to a method which uses the kit of claim 38.

Kit claims are supported by pages 75-76. In compliance with the food and drug laws, the kits will be labeled for their intended use (see Summary of the Invention) and with suitable directions for use (see pp. 40-56).